

REMARKS

This Amendment is responsive to the Office Action dated April 21, 2005. Applicants have amended claims 4, 25, 53, and 56. Claims 1–59 are pending.

Claim Rejection Under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 1, 7–10, 22, 28–31, 42–51 and 53 under 35 U.S.C. 102(b) as being anticipated by Starkebaum (US 5,733,322). Applicants respectfully traverse the rejection. Starkebaum fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, Starkebaum fails to disclose or suggest a neurostimulation lead comprising a fixation mechanism mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site, as recited by Applicants' claims 1, 22, and 42, and amended claim 53.

The Examiner stated that Starkebaum discloses a fixation mechanism mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body. However, the cited passage of Starkebaum instead describes an anchoring fixture that protrudes from a distal end of the lead, located between the most distal electrode and the distal end of the lead. Starkebaum makes no mention of a neurostimulation lead having a fixation mechanism, including one or more expandable wire-like elements, mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, as required by Applicants' claims 1, 22, 42, and 53. Moreover, upon Applicants' inspection, the reference identified by Starkebaum, U.S. Patent No. 5,344,439 to Otten, similarly fails to teach this requirement.

In order to support an anticipation rejection under 35 U.S.C. 102(b), it is well established that a prior art reference must disclose each and every element of a claim. This well known rule

of law is commonly referred to as the “all-elements rule.”¹ If a prior art reference fails to disclose any element of a claim, then rejection under 35 U.S.C. 102(b) is improper.²

Starkebaum fails to teach a fixation mechanism, including one or more expandable wire-like elements, mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, and provides no teaching that would have suggested a modification to include the feature. Instead, Starkebaum describes an anchor structure that protrudes from a distal end of a lead. By its reference to Otten, Starkebaum apparently contemplates an anchor structure that is positioned between a distal tip and a distal-most electrode. Accordingly, the teachings in the Starkebaum reference run contrary to the requirements of Applicants’ claims.

In view of the fundamental differences identified above, Starkebaum falls far short of the requirements set forth in independent claims 1, 22, 42, and 53. Of course, the claims dependent on independent claims 1, 22, 42, and 53, i.e., claims 7–10, 28–31, and 43–51, incorporate all of the limitations of the respective base claims, and therefore are patentable for at least the reasons expressed above.

Dependent claims 7–10, 28–31, and 43–51 also include a number of other features not taught by Starkebaum. For example, with respect to claims 9, 30, and 47, Starkebaum fails to disclose a restraint mechanism to restrain wire-like elements against expansion, wherein the wire-like elements expand upon removal of at least part of the restraint mechanism, and wherein the restraint mechanism includes a lead introducer, the lead introducer defining a lead introducer lumen sized to accommodate the stimulation lead body. As stated above, Starkebaum does not even describe a fixation mechanism including wire-like elements and, as such, fails to teach the use of a restraint mechanism to restrain wire-like elements against expansion, wherein the wire-like elements expand upon removal of at least part of the restraint mechanism.

As another example, Starkebaum fails to teach detaching a distal end of each wire-like element, as recited by claim 45. As stated above, Starkebaum does not even describe a fixation

¹ See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (CAFC 1986) (“it is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention”).

² *Id.*; see also *Lewmar Marine, Inc. v. Barient, Inc.* 827 F.2d 744, 3 USPQ2d 1766 (CAFC 1987); *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (CAFC 1990); *C.R. Bard, Inc. v. MP Systems, Inc.*, 157 F.3d 1340, 48 USPQ2d 1225 (CAFC 1998); *Oney v. Ratliff*, 182 F.3d 893, 51 USPQ2d 1697 (CAFC 1999); *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (CAFC 2000).

mechanism including wire-like elements and, as such, fails to teach detaching a distal end of each wire-like element. Starkebaum fails to disclose each and every limitation set forth in claims 1, 7-10, 22, 28-31, 42-51. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicants' claims 1, 7-10, 22, 28-31, 42-51 under 35 U.S.C. 102(b). Withdrawal of this rejection is requested.

Claim Rejection Under 35 U.S.C. § 103

Claims 4, 6, 12, 25, 27, 33 and 56

In the Office Action, the Examiner rejected claims 4, 6, 12, 25, 27, 33, and 56 under 35 U.S.C. 103(a) as being unpatentable over Starkebaum (US 5,733,322) in view of Sundquist et al. (US 6,567,704). Applicants respectfully traverse the rejection. The applied references fail to disclose or suggest the inventions defined by Applicants' claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

For example, neither Sundquist et al. nor Starkebaum discloses a fixation mechanism including wire-like elements including a shape memory alloy, as recited by claims 4, 25, and 56. On the contrary, in the passage cited by the Examiner, Sundquist et al. merely refers to forming flaps from a "resilient material." Sundquist et al. makes no mention of a shape memory alloy. Moreover, it is unclear why one of ordinary skill in the art would have even considered a shape memory alloy for the flaps described by Sundquist et al., much less a fixation mechanism as taught by Starkebaum.

The flaps taught by Sundquist et al. are at the distal opening of the lumen in the lead and are designed to simply flap outward when a stylet is passed through the distal opening. A shape memory alloy would seem to be undesirable as it would resist passage of the stylet in the Sundquist et al. device. Accordingly, it appears that Sundquist et al. provides no suggestion of the use of shape memory alloy, whether for flaps that are not even used for fixation, or a fixation mechanism per Starkebaum. In summary, Sundquist et al. therefore fails to disclose or suggest a fixation mechanism including wire-like elements including a shape memory alloy, and provides no teaching that would have suggested the desirability of modification to include a shape memory alloy.

As another example, neither Sundquist et al. nor Starkebaum makes any reference to a fixation mechanism including wire-like elements including Nitinol, as recited by claims 6 and 27. Nitinol is one form of a shape memory alloy. As describe above, Sundquist et al. fails to disclose wire-like elements including a shape memory alloy. Sundquist et al. similarly fails to disclose wire-like elements including Nitinol.

As another example, neither Sundquist et al. nor Starkebaum teaches a fixation mechanism including wire-like elements configured in a substantial helical shape, as recited by claims 12 and 33. Nowhere do either Starkebaum or Sundquist et al. suggest a substantial helical shape for a fixation mechanism including wire-like elements. Considering that neither Starkebaum nor Sundquist et al. discloses a fixation mechanism including wire-like elements, one of ordinary skill in the art would have found no teaching in Starkebaum or Sundquist et al. that would have suggested modification of a fixation mechanism to include wire-like elements configured in a substantial helical shape.

In addition, claims 4, 6, 12, 25, 27, 33, and 56 are patentable for the same reasons stated above with respect to independent claims 1, 22, 42, and 53, i.e., because the Starkebaum reference lacks the basic teachings attributed to it in the Office Action. Moreover, Sundquist et al. provides no teaching sufficient to overcome the basic deficiencies already evident in Starkebaum.

Claims 2, 3, 5, 11, 23, 24, 26, 32, 52, 54, 55, and 57

The Examiner rejected claims 2, 3, 5, 11, 23, 24, 26, 32, 52, 54, 55, and 57 under 35 U.S.C. 103(a) as being unpatentable over Starkebaum (US 5,733,322) in view of Sundquist et al. (US 6,567,704). Applicants respectfully traverse the rejection. The applied references fail to disclose or suggest the inventions defined by Applicants' claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

For example, neither Sundquist et al. nor Starkebaum teaches a fixation mechanism including wire-like elements having a proximal joint where the proximal end of the wire-like element meets the lead body, and a distal joint where the distal end of the wire-like element meets the lead body, wherein the distal joint is weaker than the proximal joint, as recited by claims 3, 24, and 55. The Examiner failed to point to any teaching in any prior art reference that

discloses such a feature. Furthermore, neither Sundquist et al. nor Starkebaum even describes a fixation mechanism including wire-like elements. As such, these references clearly fail to teach wire-like elements having a distal joint that is weaker than a proximal joint.

As another example, neither Sundquist et al. nor Starkebaum describes a fixation mechanism including wire-like elements including a super-elastic material, as recited by claims 5, 26, and 57. Sundquist et al. merely describes that the lead body, not a set of wire-like elements, is covered by an “insulative sleeve of flexible biocompatible and biostable insulating material, such as polyurethane or silicone rubber.” (Sundquist, col. 5, ll. 17–20). Moreover, there is no indication in Sundquist et al. of the use of a super-elastic material. Accordingly, Sundquist et al. fails to teach wire-like elements of a fixation mechanism that include a super-elastic material. Furthermore, Sundquist et al. does not even describe a fixation mechanism including wire-like elements.

In addition, claims 2, 3, 5, 11, 23, 24, 26, 32, 52, 54, 55, and 57 are patentable for the same reasons stated above for independent claims 1, 22, 42, and 53, i.e., because the Starkebaum reference lacks the basic teachings attributed to it by the Examiner. Moreover, Sundquist et al. provides no teaching sufficient to overcome the basic deficiencies already evident in Starkebaum.

Claims 13–19, 21 and 34–40

The Examiner rejected claims 13–19, 21 and 34–40 under 35 U.S.C. 103(a) as being unpatentable over Starkebaum (US 5,733,322) in view of Barreras, Sr. et al. (US 6,192,279). Applicants respectfully traverse the rejection. The applied references fail to disclose or suggest the inventions defined by Applicants’ claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

For example, neither Starkebaum nor Barreras, Sr. et al. teaches a fixation mechanism including wire-like elements, wherein one of the wire-like elements acts as an electrode for neurostimulation current, as recited by claims 14 and 35. In contrast, Starkebaum refers to the anchor mechanism of Otten (5,344,439), which consists of a plurality of lobes formed by a plurality of longitudinal slits in the flexible tubular outer casing of a catheter. The tubular outer casing described by Otten “may be of polyurethane, silicone rubber, or other biologically compatible polymer.” (Otten, col. 4, ll. 64–68). The anchor mechanism material taught by

Starkebaum via Otten is not a conductive material, and therefore cannot act as an electrode for neurostimulation current. Barreras, Sr. et al. similarly provides no teaching of a fixation mechanism including wire-like elements, one of which acts as an electrode. Neither do Starkebaum or Barreras, Sr. et al. provide any teaching that would have suggested the desirability of modification to arrive at this feature of claims 14 and 35.

As another example, neither Starkebaum nor Barreras, Sr. et al. teaches retainer rings mounted about the lead body to retain opposite ends of each of the wire-like elements, as recited by claims 13 and 34. In contrast, the rings taught by the portion of Barreras, Sr. et al. cited by the Examiner are contact rings for making electrical connection to a pulse generator, and are not coupled to any wire-like fixation elements. Neither Barreras, Sr. et al. nor Starkebaum describes a fixation mechanism including wire-like elements and, as such, both references provide no teaching that would have suggested incorporation of retainer rings to retain the wire-like elements.

In addition, claims 13–19, 21 and 34–40 are patentable for the same reasons stated above for independent claims 1, 22, 42, and 53, i.e., because the Starkebaum reference lacks the basic teachings attributed to it by the Examiner. Moreover, Barreras, Sr. et al. provides no teaching sufficient to overcome the basic deficiencies evident in Starkebaum, as described above.

Claims 20 and 41

The Examiner rejected claims 20 and 41 under 35 U.S.C. 103(a) as being unpatentable over Starkebaum (US 5,733,322) in view of Racz et al. (US 6,146,380). Applicants respectfully traverse the rejection to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicants' claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Claims 20 and 41 are patentable for the same reasons stated above for independent claims 1, 22, 42, and 53, i.e., namely, because the Starkebaum reference lacks the basic teachings attributed to it by the Examiner. Moreover, Racz et al. provides no teaching sufficient to overcome the basic deficiencies already evident in Starkebaum.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicants' claims 2-6, 11-21, 23-27, 32-41, 52, and 54-57 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

Claims 58 and 59

Applicants note that in the Office Action the Examiner addressed claims 1-57. However, Applicants' application as filed contains claims 1-59. Applicants assume this is an oversight, and respectfully request that the Examiner address claims 58 and 59 in the next communication.

CONCLUSION

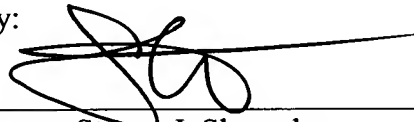
All claims in this application are in condition for allowance. Applicants respectfully request reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

10-19-05

SHUMAKER & SIEFFERT, P.A.
8425 Seasons Parkway, Suite 105
St. Paul, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

By:



Name: Steven J. Shumaker
Reg. No.: 36,275